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**Via E-Mail and
Federal Express
301-827-6860**

September 19, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01P-0120
Medical Devices; Needle-Bearing Devices

B. Braun Medical Inc., a full line supplier of innovative healthcare products and programs designed to improve both patient and clinician safety, applauds the cooperative efforts of FDA, OSHA, NIOSH, and the CDC, which recognize that education is the key to promoting the safe use of medical devices that have the potential to cause harm to the users. There can be little doubt that educating healthcare professionals about ways to prevent needlestick injuries has dramatically reduced such injuries.

We have carefully reviewed the Federal Register notice (67 Fed. Reg. 41890, June 20, 2002), the petition, and FDA's responses to the petition. We offer the following comments:

A. Banning

The petition asked FDA to ban IV catheters, blood collection devices, and blood collection needle sets that do not meet the standards established in FDA's 1992 safety alert. This safety alert says that needle-bearing devices should have a fixed safety feature that meets all of the following criteria:

- (1) It provides a barrier between the hands and needles after use;
- (2) It allows or requires the worker's hands to remain behind the needle at all times;
- (3) It is an integral part of the device, and not an accessory; and
- (4) It is in effect before disassembly, if any, and remains in effect after disposal.

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The safety alert also suggests that the device should be simple and easy to use requiring little training. The petition also proposed banning glass capillary tubes and certain IV infusion equipment.

We agree with FDA that there is insufficient data on which the agency may conclude that a particular device (or class of devices) meets the legal standard for banning a device. Because, as FDA has noted, a device may be banned only after FDA has made specific findings “on the basis of all available data and information” regarding that specific device, it is essential that FDA and industry have an understanding of, and confidence in, the data on which such findings are based.¹

Further, we are concerned that a ban based on the safety alert may have the unintended consequence of stifling research and innovation in this area. For example, a product need not necessarily provide “a barrier between the hands and needles after use,” so long as it provides a barrier between the hands and the sharps (in this case, the needle bevel) after use. Manufacturers should be encouraged to continue research and development of promising alternative methods of preventing needlestick injury using the safety alert as an important guideline. Moreover, the Needlestick Safety and Prevention Act (NSPA) requires employers and employees to review sharps devices and determine whether they may be used safely.² OSHA also recognized the important contributions that frontline workers can make with respect to acceptance and proper use of medical devices.³ An outright ban by FDA takes the authority to evaluate and select effective devices away from the very clinical personnel that NSPA was intended to empower, and inappropriately removes frontline clinical experience from the equation.

B. Performance Standard

We do not believe that performance standards are warranted. Clinical personnel are extensively trained in the safe use of medical devices, and are best able to assess risk in a clinical environment. Indeed, through the efforts of government (particularly FDA, OSHA, NIOSH, and CDC), as well as organizations such as the National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI) and the International Health Care Worker Safety Center at the University of Virginia, needlestick awareness is at an all

¹ 21 C.F.R. Part 895.

² “An employer . . . shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls. . . .” Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000).

³ See 66 Fed. Reg. 5318, 5320 (Jan. 18, 2002).

time high. Moreover, NSPA recognizes that employees responsible for direct patient care are capable of evaluating the safety of medical devices. In this environment, a performance standard is unnecessary.

C. Labeling

The petition requested that FDA require that the labeling for “conventional syringes” state: “TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS.”

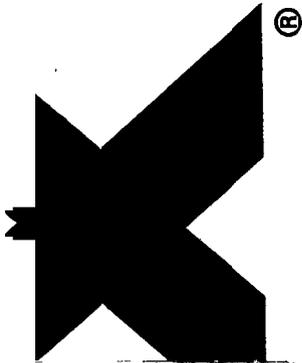
We agree with FDA that health professionals are commonly aware of this warning. Training and education are sufficient to address the risk of using devices for this purpose. A labeling requirement would simply increase the cost of the device, with no measurable reduction in risk.

We appreciate the opportunity to work together with FDA and other health care professionals on this important matter. We look forward to participating in FDA’s planned public forum.

Sincerely,

A handwritten signature in black ink, appearing to read "Sheila Kempf". The signature is written in a cursive style with a large, looped initial 'S'.

Sheila Kempf
Vice President
Marketing



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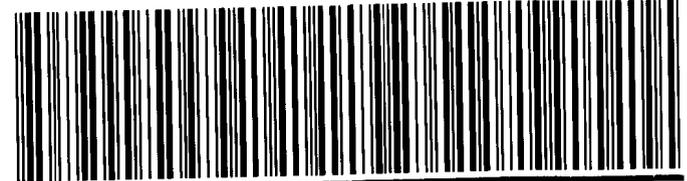
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Human Resources

September 16, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 01P-0120; Medical Devices; Needle-Bearing Devices: Request for Comments and Information

To Whom it May Concern:

I am a member of NAPPSI and want to register my support of NAPPSI's position to:

1. Publish NAPPSI's Notification to Clinicians on Sharp Injuries.
2. Disseminate information about NAPPSI's Safety Device List. This compilation lists the needlestick-safety technology of NAPPSI members and other companies, dividing them into "primary prevention" and "seconadry prevention" categories. All needlestick-safety devices are included and displayed in a manner most helpful to safety-conscious clinicians.
3. Involve NAPPSI in discussions aimed at creating a voluntary consensus standard for devices listed in the HRG?SEIU petition, such as IV catheters and infusion equipment that do not have safety features.

Sincerely,

A handwritten signature in cursive script that reads "Judith Podgorny R.N."

Judith Podgorny, RN, MSN, COHN-S
Employee Health Nurse

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Occupational Health services



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Food and Drug Administratio
5630 Fishers Lane, Room 101
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Judith Podgorny, RN, MSN, COHN-S
Employee Health Nurse

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